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In the Supreme Court of the United States

OCTOBER TERM, 1948

No. 13

UNITED STATES OF AMERICA, PETITIONER

v.

FRED URBETEIT, CLAIMANT OF 16 ARTICLES OF DEVICE, MORE OR LESS, LABELED "SINUOTHERMIC," ETC.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE UNITED STATES

OPINION BELOW

The opinion of the Court of Appeals (R. 179–183) is reported at 164 F. 2d 245.

JURISDICTION

The judgment of the Court of Appeals was entered on November 7, 1947 (R. 183). The petition for a writ of certiorari was filed on February 6, 1948, and was granted on April 19, 1948 (R. 185). The jurisdiction of this Court was invoked under Section 240 (a) of the Judicial Code, now 28 U. S. C. 1254.

QUESTIONS PRESENTED

Certain devices, and leaflets claiming that the devices were useful in the diagnosis and therapy of numerous ailments, were shipped in interstate commerce by respondent to the same consignee, but separately and at different times. The leaflets were sent for the purpose of describing the capabilities of the device to prospective purchasers and users; the leaflets and device were displayed together, and the device itself bore no labeling other than name and serial number.

The principal question presented is whether, as a matter of construction of the pertinent interrelated provisions of the Federal Food, Drug, and Cosmetic Act, the device is subject to condemnation. Section 304 (a) provides for the condemnation of any device that is "misbranded when introduced into or while in interstate commerce"; Section 502 (a) defines a device as "misbranded" if its "labeling" is false or misleading in any particular; and Section 201 (m) defines "labeling" to include "written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article".

Subsidiary questions are whether the evidence supports the district court's finding that the "labeling" of the device was false and misleading in respect of the representations regarding its diagnostic capabilities; and, if so, whether the

Government is therefore entitled to a decree of condemnation, even assuming that the district court improperly excluded certain evidence offered by respondent to substantiate the representations regarding the therapeutic value of the device.

STATUTORY PROVISIONS INVOLVED

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 (21 U. S. C. 301, *et seq.*), are set forth in the Appendix, pp. 43–44.

STATEMENT

The Pleadings. On January 9, 1947, a second amended libel of information was filed in the United States District Court for the Northern District of Florida, under Section 304 of the Federal Food, Drug, and Cosmetic Act, seeking the seizure and condemnation of 16 "articles of device" labeled "Sinuothermic" (R. 11–15). The libel alleged that the device was "misbranded" within the meaning of Section 502 (a) of the Act because its "labeling" was false and misleading. In particular, the libel alleged that the device was "accompanied" in interstate commerce by a leaflet entitled "The Road to Health", containing false and misleading representations regarding the curative and therapeutic powers of the device in the diagnosis, cure, mitigation, treatment, and prevention of disease (R. 13).

Fred Urbeteit, the respondent, who is a naturopathic physician (R. 119), appeared as claimant of ten of the devices of the so-called treating unit type (R. 5, 12, 10), and J. J. H. Kelsch, an unlicensed naturopathic and chiropractic physician (R. 32), appeared as claimant of the remainder of the devices, two of which were the so-called master units and four of which were of the treating unit type (R. 5, 12, 10). Together they filed a "consent to amendment and claim" which admitted factual recitals in previous pleadings, renewed the statements of ownership, and admitted that the sixteen devices and a number of leaflets, entitled "The Road to Health", were introduced into interstate commerce at Tampa, Florida, for shipment to Cincinnati, Ohio, and were in possession of Kelsch at Cincinnati when the libel was filed. They denied that the devices and leaflets were shipped together or that they related to each other, and neither admitted nor denied the dates of the shipments because of lack of exact knowledge. They also denied that the leaflets accompanied the devices in interstate commerce and that the representations made in the leaflets were false or misleading. (R. 10–11, 11–15.)

The Evidence. The case was tried by the court without a jury (R. 15). The evidence showed that Urbeteit was the shipper (R. 24, 29–31). Four shipments of the devices were made by means of the Railway Express Agency, the first

on July 23, 1945, the second on August 14, 1945, the third on August 18, 1945, and the fourth on September 21, 1945 (R. 24–25).

Kelsch testified that he had received a three weeks' course of instruction from Urbeteit in Florida in June 1945, and had received a diploma in absentia (R. 25–26). While there, arrangements were made for the purchase of some devices and for the rental of others, contingent upon Kelsch's ability to make financial arrangements in Cincinnati (R. 29). As a part of the same transaction, Urbeteit agreed to supply a quantity of the leaflets, "The Road to Health", for the purpose of explaining the machines to Kelsch's patients (R. 29). Accordingly, the leaflets were shipped to Kelsch in bulk supply and received by him. Pursuant to an understanding between Kelsch and Urbeteit, some of the leaflets were mailed out to patients and others were shown to patients during consultation. (R. 29–30.)

Kelsch first testified that he received the leaflets, by parcel post, after the machines were shipped to him (R. 29, 6), but later stated that he did not know the exact date the leaflets were received. He stated that they were received sometime around September (R. 31). Some of the leaflets were found on September 5, 1945, in and on a desk in Kelsch's main consulting room within the reach and view of patients who consulted him there. The devices were in the ad-

joining consulting rooms and treating rooms. The devices bore a label which contained the statement "U. S. Patent Sinuothermic Trade Mark" together with a serial number (R. 20). No labeling other than the leaflets, "The Road to Health", was sent to Kelsch. Some machines were sold or rented to patients by Kelsch (R. 22–23, 30).

In addition to many representations of therapeutic value involving, among many others (see R. 165), such variegated diseases as cancer, tuberculosis, diabetes, appendicitis, heart disease, hay fever, infantile paralysis, menstrual discomfort, peritonitis, nervousness, and prostate trouble, the leaflet, "The Road to Health",[1] in part describes the diagnostic capabilities of the machines as follows:

IMPORTANCE OF EXAMINATION

> You must realize the all importance of being examined the Sinuothermic way, which leaves out all guess work as Sinuothermic locates the cause and registers exactly [p. 1, col. 3].
>
> * * * * *
>
> CANCER DANGER SIGNAL
>
> * * * At the Sinuothermic Institute no one is ever treated without first being thoroughly examined, and it should be remembered that NO really COMPETENT doctor

[1] This exhibit (R. 13, 19) is on file with the Clerk of this Court. Reproductions of this exhibit have also been filed with the Clerk.

will treat a condition that might be a cancer without first making a careful examination. INSIST on a thorough examination no matter who your doctor is. Be examined with Sinuothermic which registers exactly and never makes a mistake [p. 1, col. 4].

* * * * *

BE EXAMINED

Why have someone guess at what your ailment is when at the Sinuothermic Institute, Inc., you can be examined with that never failing Sinuothermic machine which leaves out all guess work and registers exactly [p. 1, col. 4].

SINUOTHERMIC EXAMINATION

Dr. Urbeteit told them that he could not tell them anything until he examined her with Sinuothermic. The examination revealed that she not only had a tumor in the uterus but she was also pregnant about 5 months. * * * [p. 2, col. 6]

* * * * *

SCIENCE AT ITS PEAK

Sinuothermic is the last word in scientific discoveries. Sinuothermic is a tester of human tissue. You could liken Sinuothermic to the tester they use to test your radio tubes with * * * Sinuothermic registers exactly the condition of human tissue [p. 2, col. 6].

The general representation that the machine "locates the cause of any ailment and registers exactly" appears frequently throughout the leaflet.

The Government's evidence showed that the Sinuothermic machine consists of a number of electrical units mounted in a wooden cabinet (R. 39). The machine is designed to draw electricity from an ordinary household wall socket, to control the full line voltage (electrical pressure) by turning in variable amounts from zero to the full line voltage (115–120 volts), to step this voltage down to a maximum value of 60 volts, and to deliver current to the patient so that it will flow through the body between two pad electrodes that are applied to the bare skin (R. 39–44, 50–52, 164). The small machines differed from the master units only in the omission of the four indicating meters (R. 43, 164).

The Government's evidence showed, further, that even the master model, which had four indicating meters, was incapable of registering any pathological changes in the body. This was because the meters were primarily affected by the patient's body resistance to electrical current and because internally the current is conducted through body fluids and not body tissues (R. 43, 51–52). The so-called treating units did not have the four indicating meters (R. 43). The expert testimony for the Government was that these machines were without value in the diagnosis of

the disease conditions involved (R. 72, 76, 79–80, 83–85, 88–89, 91, 93, 96–97, 99–100, 104–105, 109–112).

Urbeteit described his method of "diagnosis" as follows: he said that when the current from the machine encounters a lesion in the human body, the meters will register "the amount of intensity or resistance there is in that particular area" (R. 126–127, 128–130). He admitted, however, that the machines alone are incapable of diagnosing any specific disease:

> The meters do not tell me what the ailment is, it merely registers when it is below normal. If it is normal it has a free flow; if it is not normal it has the obstructed flow, and according to the amount of obstruction that also indicates the severity of the ailment itself. Then the doctor, himself, should know from other tests what the ailment is * * * [R. 129].
>
> * * * * * * * *
>
> There is no way of registering the kind of ailment or the name of an ailment. It merely locates where there is something wrong. Then whatever that something is wrong it is necessary then to take chemical tests; or whatever tests is necessary to determine the name of the ailment that can also be done. But I find in all my experience it is not necessary to go to all that trouble to take those tests. As long as the patient gets well, that seems to be the first requisite [R. 129–130].

The expert testimony for the Government contradicted this claim that the machine could "locate where there is something wrong" (R. 76, 79–80, 93, 96–97, 99–100, 104–105, 109–112).

The respondent offered to present testimony by various patients as to the benefits they had received through use of the device. The trial court excluded this testimony on the ground that it was offered (1) as opinion evidence on medical questions and was thus incompetent, or (2) as hearsay evidence as to what some physician not in attendance at the trial had told the patients as to their diseases. (R. 160–163.) The court also excluded testimony by respondent as to "diagnoses" made by him through use of the machine (R. 131, 159–161, 163).

The Findings. The trial court found (1) that the leaflets entitled "The Road to Health" accompanied the devices while in interstate commerce (R. 164); (2) that the leaflets claimed diagnostic values and therapeutic effects for the machines in many conditions (R. 165, Finding 4) and that they represented that the machine will register the exact nature of any disease (R. 165, Finding 5); (3) that the master model was incapable of diagnosing disease by registering pathological changes in the body (R. 165–166, Finding 5); and (4) that the principles on which the machines were claimed to operate were impossible of practical application with these instruments (R. 166, Finding 7). (The falsity of the claims of diag-

nostic capabilities for the small models was treated under the latter general finding). The court also found that the claims of therapeutic and curative effect were false and misleading (R. 166).

The Rulings Below. The district court, concluding that the devices were shipped in interstate commerce and misbranded in violation of the Act, held that the Government was entitled to a decree of condemnation (R. 167), which was entered on January 27, 1947 (R. 168–169). Upon appeal to the Court of Appeals for the Fifth Circuit, by Urbeteit alone, the judgment was reversed and the cause remanded for further proceedings (R. 179–183) on the grounds (1) that the leaflets had not "accompanied" the devices while in interstate commerce and hence did not constitute labeling within the meaning of the Act,[2] and (2) that the trial court had erred in excluding the testimony offered by respondent. The Court of Appeals held that the respondent's patients should have been permitted to state whether their external symptoms abated and their pains ceased (R. 182–183); and that Urbeteit, as "a licensed doctor of some twenty years practice," should have been permitted to "express expert opinions" on the efficacy of his machine (R. 182–183).

[2] Although it did not expressly so hold, the court indicated [redacted] that the leaflets could not properly be considered as labeling for the machines because they were more in the nature of advertising (R. 181–182). See pp. 32–37, *infra*.

SUMMARY OF ARGUMENT

I

A. The history of federal food and drug legislation is essentially empiric: it is a chronicle of the successive efforts by Congress to plug one loophole after another through which the unscrupulous have been able to frustrate the purposes of the legislation. In 1938, after a series of ineffectual amendments to the old 1906 law, Congress enacted a broad and comprehensive measure, the Federal Food, Drug, and Cosmetic Act, which, it was hoped, would at last "meet the requirements of consumer protection under modern conditions" (see *infra*, p. 19).

The principal question presented in this case and in *Kordel* v. *United States* (No. 30) is, essentially, whether Section 201 (m) of the 1938 Act contains an easy loophole which reduces it to an empty formulation of words having no practical significance. In particular, the issue is whether the court below is right in holding that the words "accompanying such article," as used in Section 201 (m), require that article and leaflet must travel together in interstate commerce over the same route and at the same time. The court below rejected the Government's contention that the concept of "accompaniment" is a practical one, governed by considerations based on economic realities and common-sense. We be-

lieve with this Court (see *United States* v. *Dotterweich*, 320 U. S. 277, 280) that regard for its humanitarian purposes "should infuse construction of the legislation".

The Government submits that a leaflet which (a) explains the uses to be made of a device, (b) is sent in interstate commerce by the same shipper to the same consignee, and (c) is displayed with and is intended to be distributed with the device, "accompanies" the device for all practical purposes, and therefore should also be regarded as "labeling" for purposes of the statute, even though the leaflet is shipped separately and at a different time from the device. Otherwise, if the court below is right, the unscrupulous have a ready-made means for evasion of the salutary purposes of the Act.

B. Printed matter can constitute both advertising and labeling; it does not necessarily lose its character as labeling because it has some characteristics of advertising.

II

The leaflets contained representations as to both the diagnostic and therapeutic capabilities of the machine. The evidence excluded by the trial court related only to the alleged therapeutic value of the machine. The evidence overwhelmingly established the falsity of the claims regarding diagnostic capabilities. Since a decree of condemnation can properly issue if it is shown that

any one of the various claims in the labeling is false, the Government is entitled to a decree of condemnation, even if it be assumed that error was committed in excluding evidence as to the therapeutic powers of the machine.

ARGUMENT

Preliminary Analysis. In order to prevail in this case, the Government had to prove the following: (1) That respondent's machines constituted a "device"; (2) that the device was "accompanied" by leaflets which constituted "labeling"; (3) that these leaflets were false or misleading, and hence that the device was "misbranded"; and (4) that the device was misbranded "when introduced into or while in interstate commerce."

No contention is made that the Sinuothermic machine is not a "device". Nor is there, in our view, any serious question as to the false and misleading character of the leaflets, "The Road to Health". The principal question is whether the court below erred in ruling, as a matter of law, that the leaflets did not "accompany" the device, and that consequently the latter was not "misbranded when introduced into or while in interstate commerce." This ruling required dismissal of the libel; but the court below went on to hold that the trial court had erred in excluding certain evidence offered by respondent and that the "case ought to have been more fully

tried" (R. 183). This latter ruling would, in itself, require only a remand for a new trial. The judgment formally entered by the court below was that the decree of the district court should be reversed and the cause remanded for further proceedings consistent with its opinion (R. 183).

In this posture of the case, the Government urges here that the decree entered by the district court was correct in all essential respects and should be reinstated without further proceedings. In our view the district court's construction of the Act was proper and a decree of condemnation should issue, even assuming that error was committed in excluding respondent's offer of proof, because such proof related only to the alleged therapeutic value of the device; the findings as to the false and misleading character of the representations regarding the diagnostic powers of the machine are amply supported by the evidence, and in themselves form a sufficient basis for the decree.

I

RESPONDENT'S DEVICE WAS "ACCOMPANIED" BY FALSE AND MISLEADING LEAFLETS, AND HENCE WAS "MISBRANDED WHILE IN INTERSTATE COMMERCE."

The essential difference between the construction made by the court below and that urged by the Government relates to the word "accompanying" in Section 201 (m), which provides:

For the purposes of this Act—

* * *

The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

The court below held that, because the leaflets and devices did not travel together or at the same time during the interstate journey, the leaflets "did not accompany any of the devices while they were in interstate commerce * * *. Accompany means to go along with. In a criminal and forfeiture statute the meaning cannot be stretched." (R. 181).

This in effect lays down the rule that there must be physical association of the printed matter and article during the movement in the channels of interstate commerce. We think that such a construction of the word "accompanying" is unduly narrow; and that, correctly construed, a leaflet which for all practical purposes is incident to and an integral part of the distribution of an article "accompanies" that article, even though it has no physical connection with the article during its interstate journey.

There can be no doubt as to the underlying purpose of the Federal Food, Drug, and Cosmetic Act. It was carefully devised to protect the ultimate consumer from misbranded and adulterated food, drugs, devices and cosmetics from the time they enter the channels of commerce until they

are purchased for consumption or ultimate use. *United States* v. *Sullivan*, 332 U. S. 689. In *United States* v. *Dotterweich*, 320 U. S. 277, 280, this Court said:

> The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.

Nothing in the purposes or history of the Act indicates that Congress intended that its beneficial protective provisions could be evaded by the simple expedient of separate shipment of an article and the printed explanatory matter which, in a practical business sense, "accompanies" it.

The Food and Drugs Act of 1906 (Section 8) originally applied the term "misbranded" to "the package or label of [a drug or article of food] which shall *bear* any statement, design, or device regarding such article * * * which shall be false or misleading in any particular * * *" (Italics supplied) (34 Stat. 768, 770). This language was held inapplicable to false or misleading circulars enclosed in the package with the article. *United States* v. *American Druggists' Syndicate*, 186 Fed. 387, 391 (E. D. N. Y.).

The Act was promptly amended [37 Stat. 416; 21 U. S. C. 10 (1934 Ed.)] to provide that a

drug[3] was to be deemed misbranded "If its package or label shall *bear or contain* any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent." (Italics supplied). The word "contain" was inserted by the 1912 amendment to cover circulars or printed matter placed within the package. *Seven Cases of Eckman's Alterative* v. *United States*, 239 U. S. 510.

Notwithstanding this amendment, unscrupulous purveyors of nostrums were able readily to circumvent the law by adopting the practice of shipping, separate from the drug to which it related and which it described, printed matter containing false and fraudulent claims. Thus, prior to 1938, the law protected the public only where false claims were made on the label or package or on circulars within the package. It was obvious, however, that there was need for extending consumer protection to printed or graphic matter associated with and distributed in relation to an article but which appeared outside its package.[4]

[3] The Food and Drugs Act of 1906 did not cover therapeutic devices. Under the present Act, drugs and devices are similarly treated wherever possible. Compare § 201 (g) (2) and (3) with § 201 (h), and see §§ 501 and 502.

[4] This need was recognized by the persons charged with enforcement as early as 1917, when the Food and Drugs Act of 1906 had been effective for only 10 years. The Annual Report of the Bureau of Chemistry for that year contained a review of 10 years of enforcement and recommendations

The 1938 revision was considered in Congress as early as 1933. Many bills were introduced and discussed during the 5-year period of legislative consideration. Congress, by its responsible committees, expressed its clear purpose that the new law "must not weaken the existing laws", but "must strengthen and extend that law's protection of the consumer." S. Rep. No. 152, 75th Cong., 1st Sess., p. 1. The purpose of the 1938 enactment was stated in H. Rep. 2139, 75th Cong., 3rd Sess., p. 1, as follows:

> While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in scope to meet the requirements of consumer protection under modern conditions.
>
> The measure contains substantially all of the features of the old law that have proved valuable in promoting honesty and fair dealing. But it amplifies and strengthens the provisions designed to safeguard the public health and prevent deception, and it extends the scope of the law to include cosmetics, therapeutic devices, and certain drugs that now escape regulation.

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for closing loop-holes in the Act of 1906. The report stated in part: "* * * the law fails to take cognizance of fraudulent statements covering foods or drugs which are not in or upon the food or drug package." Amendatory legislation was suggested, but it was not until 1933 that such legislation was offered. In that year, a general revision of the Act was proposed. S. 1944, 78rd Cong., 1st Sess.

See *United States* v. *Dotterweich*, 320 U. S. 277, 280, 282.

Walter G. Campbell, then Chief of the Food and Drug Administration, explained the purpose of the definition of labeling at the Hearings Before a Subcommittee of the Committee on Commerce, United States Senate, 73rd Congress, 2nd Sess., on S. 1944,[5] p. 16:

> At the present time the law has control over those statements that are attached to or that accompany the package in the form of circulars. For the purposes of the subsequent requirements of this bill these have been divided into two classes; first, "label" meaning the principal label or labels upon the immediate container of any food, drug, or cosmetic, and upon the outside container or wrapper, if any there be, of the retail package of any food, drug, or cosmetic. Then the term "labeling" is defined so as to include not only the label but all circulars and material and placards for display purposes and the like that may in any form whatever accompany the article of food, drug, or cosmetics.

Clearly, therefore, the 1938 Act made the concept of "labeling" more comprehensive than that which existed under the earlier law, so that it would include not only the label and material within the package, but also all written, printed,

[5] Devices were included within the definition of drug in this bill. [S. 1944, Sec. 2 (b)].

or graphic matter in any way accompanying the article to which it relates. To paraphrase what this Court said in *United States* v. *Walsh*, 331 U. S. 432, with respect to another provision of the Act, it is impossible to say that the framers of the 1938 Act added the new language of 21 U. S. C. 321 (m) for the useless purpose of achieving the same result as had been reached under the 1906 Act without such language.

The Government submits that the proper construction of "accompaniment" should be governed by economic realities, viewed in the light of the objectives of the Act. "Accompaniment" expresses a relationship between article and labeling which is to be ascertained on the basis of a practical, common-sense judgment. To hold, as the court below did, that identity of time in transit is an essential requisite of "accompaniment" is, we submit, justified by neither the terms nor purposes of the Act. Transportation factors are relevant, but not controlling, in determining whether article and labeling are so integrally related as to constitute "accompanying" elements of a single interstate transaction.

The construction made by the court below is in conflict not only with that made by the Court of Appeals for the Seventh Circuit in the companion case, *United States* v. *Kordel*, 164 F. 2d 913 (No. 30, this Term), but also with the rulings of other federal courts. See *United States* v. *Re-*

search Laboratories, 126 F. 2d 42 (C. C. A. 9), certiorari denied, 317 U. S. 656; *United States* v. *Lee,* 131 F. 2d 464 (C. C. A. 7); *United States* v. *One Dozen Bottles, etc., Boncquet Tablets,* 146 F. 2d 361 (C. C. A. 4); *United States* v. *One Device* * * * *Colonic Irrigator,* 160 F. 2d 194, 195–196, 200 (C. C. A. 10); *United States* v. *7 Jugs* * * * *Rakos,* 53 F. Supp. 746, 756 (D. Minn.); *United States* v. *Paddock,* 67 F. Supp, 819, 68 F. Supp. 407 (W. D. Mo.); but cf. *Alberty* v. *United States,* 159 F. 2d 278 (C. C. A. 9).*

In the *Kordel* case, the court said (No. 30, R. 462–464):

> It is now generally held that in order to support a misbranding charge under the Act as amended and revised in 1938, it is not necessary that the matter alleged to accompany the product be shipped in the same container * * * nor even that it be shipped simultaneously * * *.
>
> * * * * *
>
> We agree with appellee that the "correct concept of 'accompaniment' is one of com-

* Although there are fifteen states with comparable provisions in statutes patterned after the Federal Act, there are no reported state decisions interpreting the phrase "accompanying such article." States having statutes drafted according to the outline of the Federal Food, Drug and Cosmetic Act are: California, Connecticut, Florida, Indiana, Louisiana, Massachusetts, Missouri, Nevada, New Jersey, New York, North Carolina, Oregon, Tennessee, Virginia and Washington. See for example Florida Stat. (1941), Secs. 500.01–500.32.

> mercial or business association". * * *
>
> We, too, are convinced that the test is not of physical contiguity but of textual relationship * * *
>
> We agree with the District Court that, because the literature was shipped by appellant or at his order, to the same consignees as the products, related to those products, and was intended to be disfributed in relation to them, it did accompany the products into interstate commerce within the definition of the Act. * * *

The Government's construction of "accompaniment" was set forth with exceptional lucidity in *United States* v. *7 Jugs* * * * *Rakos,* 53 F. Supp. 746, 755 (D. Minn.):

> * * * it is simply a question of determining in a given case whether the relationship between the article and the printed matter is sufficiently proximate to fulfill the requirement of accompaniment.
>
> * * * * * *
>
> * * * the printed matter and the drugs had a common origin. They had a common destination in that both were intended to come together in the stores of dealers * * *. They were interlocking units of a distributional scheme the objective of which was ultimate association and distribution together. * * * It is fair to conclude that these booklets were prepared, shipped and distributed to dealers with the ultimate expectation and intention on

the part of the Laboratories that they would serve the purpose of labeling for the three articles of merchandise here involved. Without the booklets, the products themselves lacked labeling, at least in so far as informing purchasers of the purposes and uses of the remedies. The mere fact that the products were shipped at a different time, over a different route and were received at a different time from the booklets should not be permitted to confuse or obscure the substance of the matter. The instant that the product Rakos entered the channels of commerce enroute to the Hatcheries, it was to all intents and purposes as much travelling in accompaniment of the representations contained in the booklets as if those booklets were actually enclosed in the same shipping container * * *

Were not the factors just stated to be given primary consideration, there would be a multiplication of refinements. * * * The physical aspects of the transportation are not important. What is vital here are such factors as interdependence of the drug and the booklets, common origin, common destination, display, distribution and use together. These determine whether there has been that degree of accompaniment which provides the necessary "misbranded" status under Section 304 (a). The mere fortuitous circumstance of an absence of physical association between the booklets and drugs during the interstate

journey of the drugs does not in my opinion control.

Here, as in the *Rakos* case, the devices and leaflets were interlocking units of a distributional scheme, and the leaflets described the purposes and uses of the devices. The leaflets were intended to be used not only by Kelsch, the consignee, but also by patients he treated and to whom he sold devices. Pursuant to understandings between Kelsch and Urbeteit, some of the leaflets were mailed out to patients and others were shown to patients during consultation (R. 30). The devices bore no information as to their purposes and intended uses. Without the leaflets, the devices lacked labeling; nowhere else is the user advised of the purposes to which the machines were to be put. The machines and leaflets were designed to be used together in furtherance of the use and commercial distribution of the machines. In a practical business sense the booklets did accompany the device as a part of a single transaction and distributional scheme from the inception of the interstate movement of each of the machines.

If the court below is correct, it would be necessary in every case to show a physical connection in the interstate movement of articles and printed material. Movement on the same train, truck, or other vehicle would be required as a practical matter, for only then could it be shown

that the articles and leaflets accompanied each other in interstate commerce. False representations as to the capabilities of diagnostic and therapeutic devices would in large measure thus be removed from the protective coverage of the Act. Such devices frequently do not go to their consignees in consumer sized packages. Many of them are bulky—as are the Sinuothermic machines—and a common practice is to ship the labeling separately. Items of printed matter identical in content, designed for the purpose of explaining the uses of a drug or device and intended to serve the purposes of labeling, would or would not constitute labeling, depending upon the accident of physical association at the time of transportation.

There would be no doubt, even under the construction of the court below, that these leaflets would constitute labeling if they had physically traveled together with the machines in interstate commerce. All that respondent did was to break this physical attachment, and whether for convenience or to evade legal requirements, he made separate shipment of device and leaflets. All other ties, except physical association in transit, remain. Without the machines, the leaflets had no purpose; and without the leaflets the machines could not easily be put to commercial use.

We find it impossible to believe that Congress intended to attach such significance to a severance in

physical proximity during the interstate journey. If physical association be the test, the result would be that printed matter sent on one day would constitute labeling while the same printed matter if sent only one day before or after would not constitute labeling, depending on whether the article to which it relates was in transit at the same time. The shipper would need only assure himself that machine and labeling were not moving in commerce simultaneously. Under the construction of the court below, the leaflet would not be labeling even though article and printed matter were presented to the consumer at exactly the same time.

The Act is concerned with distribution of articles (*United States* v. *Dotterweich*, 320 U. S. 277, 283), and the appropriate inquiry is whether the ultimate purchaser will be misled (*United States* v. *Two Bags* * * * *Poppy Seeds*, 147 F. 2d 123, 127 (C. C. A. 6)). As was said in the *Rakos* case, 53 F. Supp. 746 at 754, "misbranding has true significance only in terms of the consumer." Section 201 (m) is indeed but a futile gesture if the essential inquiry in its application goes only to the time the device and leaflet were in commerce, without regard to the substance of the transaction and its effect upon the consumer.

The court below mistakenly thought that its construction of "accompany" was required by the literal meaning of the word. "Accompany", the

court said, "means to go along with. In a criminal and forfeiture statute the meaning cannot be stretched" (R. 181). It is far from clear, however, that the word "accompany" necessarily means *physical* contiguity. It should be noted, first, that the word is not defined in the Act. Secondly, the Government's construction is included among common dictionary definitions. Webster, for example, defines "accompany" to mean "to cause to be attended by," "to go with or attend as a companion or associate", "to go along with", and "to occur in association with" (New International Dictionary, 2d ed. 1948). The Oxford English Dictionary definitions include "to supplement [a thing] by [another]", "to go in company with", and "to associate, consort, or keep company with" (Murray ed. 1888). The synonyms given by Funk and Wagnalls include "escort, follow, join, wait on" (New Standard Dictionary, 1947).

Congress is familiar with the usage of the word "accompany" in the sense which we suggest. Every committee report prepared for the purpose of explaining proposed legislation to members is marked: "REPORT To accompany S. —" or "REPORT To accompany H. R. —". There is in that usage nothing more than the textual relationship of the report to the bill. No idea of physical attachment is necessarily intended.

It will be argued that, even if the leaflets "ac-

companied" and hence "misbranded" the device, it does not follow that the device was misbranded "when introduced into or while in interstate commerce", as required by Section 304 (a). According to this contention, the device was misbranded, if at all, only after its shipment in interstate commerce had been completed.

The answer to this argument is to be found in the history of the applicable statutory provisions. Section 304 (a) of the present Act is derived from Section 10 of the old 1906 Act, 34 Stat. 768, 771, 21 U. S. C. A. 14. Under Section 10, seizure was available as to any "article of * * * drug * * * that is * * * misbranded * * * and is being transported from one State * * * to another * * *". As has been shown above, pp. 17–18, the concept of "misbranding" under Section 8 of the 1906 Act was narrowly restricted to printed matter in the package or on its label; accordingly, Section 10 was framed in terms of actual physical misbranding during the interstate journey of the article.

However, Congress has in the present Act expanded the concept of misbranding beyond this limited area of actual physical contiguity of article and labeling. An article is now "misbranded" under the Act if its labeling, whether it be printed matter on the article, or any of its wrappers or containers, or "accompanying" it, is false or misleading. To hold that, in circum-

stances such as are here present, the device is "misbranded" but not while "in interstate commerce", is to hold that Congress has expanded the words but not the substance of the 1906 Act. It would mean that the substantive amendments made by Congress to enlarge the scope of "labeling" are entirely nugatory because it failed to adjust similarly the jurisdictional provisions in Section 304 (a). This would for practical purposes require that "accompanying" be construed to mean physical attachment, and the purpose of Congress to close loopholes in the 1906 law will have been thwarted.

It is respectfully submitted that where, as here, the device is misbranded in the hands of the consignee because of false and misleading printed matter which was sent to him separately and at a different time, the printed matter "accompanied" the device and the latter was misbranded from the instant that it entered the channels of commerce. The interstate transaction must be viewed in its entirety as a single interrelated episode; and the Act is not to be eviscerated by reading the jurisdictional provisions of Section 304 (a) into the definition of labeling so as to deprive the phrase "accompanying such article" of all significant meaning.

The Act was not directed towards the abstract goal of purifying the "channels" of interstate commerce. As was stated in *United States*

v. *Sullivan*, 332 U. S. 689, 696, "the Act as a whole was designed primarily *to protect consumers* from dangerous products" (italics added). This precise contention was discussed by the Court of Appeals for the Seventh Circuit in *United States* v. *Lee*, 131 F. 2d 464, 466:

> It [the Act] was enacted to protect the public health and to prevent fraud, and it ought to be given a liberal construction. Consequently, we are impelled to the conclusion that misbranding is cognizable under the Act if it occurs while the articles are being held for sale.

The Food and Drug Administration of the Federal Security Agency, which has responsibility for enforcement of the Act, has placed an authoritative administrative construction on these provisions. Its Regulation (set forth in the Appendix, p. 45) provides:

> Labeling includes all written, printed, or graphic matter accompanying an article *at any time* while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce. [Italics added.] [1]

[1] This common-sense construction is reinforced by the amendment made to the Act by Public Law 749, 80th Cong., 2d Sess., approved June 24, 1948. The amendment, though inapplicable to the present case, inserted in Section 304 (a) immediately after the words "when introduced into or while in interstate commerce" the following: "or while held for sale (whether or not the first sale) after shipment in interstate

B. ADVERTISING MATTER IS NOT EXCLUDED FROM THE DEFINITION OF LABELING

Although it did not expressly so hold, the court below indicated doubt that the leaflets could properly be considered labeling for the machines because it thought the leaflets were more in the nature of advertising (R. 181–182).

The fact that the leaflet "The Road to Health" has some of the characteristics of advertising does not exclude it from the l a b e l i n g definition. Nothing in the Act suggests that labeling and advertising are mutually exclusive. An item of printed matter may at once serve the dual purpose of advertising and labeling. In the *Kordel* case, the court said (No. 30, R. 463):

> * * * labeling and advertising are not mutually exclusive, and the same matter may serve both purposes.

In *United States* v. *Research Laboratories*, 126 F. 2d 42, 45 (C. C. A. 9), certiorari denied, 317 U. S. 656, the court said:

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commerce." This amendment was deemed necessary because of the decision in *United States* v. *Phelps-Dodge Mercantile Co.*, 157 F. 2d 453 (C. C. A. 9), certiorari denied, 330 U. S. 818. In that case it was held that the law did not authorize seizure of a food which became contaminated while stored in a warehouse where it was placed after its interstate journey. The committee reports on the amendment state that the *Phelps-Dodge* decision "resulted in frustration" of the intent of the 1938 Act and "thus revealed a serious defect in the present law." See H. Rep. No. 807, 80th Cong., 1st Sess., p. 2; S. Rep. No. 1221, 80th Cong., 2d Sess.

> Appellee contends that the circulars constituted advertising and, therefore, did not constitute labeling within the meaning of the Act. The contention assumes that printed matter (such as a circular) cannot constitute both advertising and labeling. This assumption is unwarranted. Most, if not all, labeling is advertising. The term "labeling" is defined in the Act as including all printed matter accompanying an article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.

Congress' exclusion of labeling from the definition of "false advertisement" in the Federal Trade Commission Act, 15 U. S. C. 55 (a), implicitly recognizes that labeling and advertising matter are overlapping terms. The definition reads in part:

> The term "false advertisement" means an advertisement, other than labeling, which is misleading * * *."

This definition and that of "labeling" in Section 201 (m) clearly indicate that advertising which serves the purpose of labeling, as do the circulars here, is within the reach of the Federal Food, Drug, and Cosmetic Act.

The leaflets here were prepared by the respondent, and were supplied by him to the consignee for the purpose of explaining to prospective purchasers, renters, and patients the usefulness of

the device and how it is employed in the diagnosis, cure, mitigation, and treatment of various diseases. The label of the device bore only "U. S. Patent Sinuothermic Trade Mark" (R. 20). Obviously, such a label does not explain the purposes for which the device was intended to be used, but the leaflet did contain that information in elaborate detail. Thus, the leaflets were intended to and did serve the purposes of labeling equally as much as if they had been physically attached to the machines. Without the extravagant claims made in the leaflets it is doubtful that the devices could be rented or sold or that the services of the machines could have been sold to patients.

If drugs and devices are not subject to the prohibition of the Act because printed "advertising" matter relating to them is sent separately, then unscrupulous or disingenuous distributors have a made-to-order plan to evade the Act. And the practice of shipping printed matter separately from drugs and devices is wide-spread.*

* Since the enactment of the law in 1938, it has become a common practice among those intent on evasion to ship articles separately from leaflets, circulars, and booklets containing false claims made to further the distribution of such articles. The Food and Drug Administration has been equally active in contesting these evasive schemes. Between the date of the *Research Laboratories* opinion, February 24, 1942, and May, 1948, 870 Notices of Judgment have been published in cases involving drugs and devices actionable under the Federal Food, Drug, and Cosmetic Act. A survey of the cases reported in those Notices of Judgment reveals that "ac-

The court below suggests that testimonials and case histories cannot properly be regarded as labeling. The answer to this suggestion was made in *United States* v. *John J. Fulton Co.*, 33 F. 2d 506, 507 (C. C. A. 9):

> * * * if, as is alleged, the drugs are worthless, the proprietors cannot escape re-

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companying" printed matter has been involved in 348 cases. This figure includes cases in which the literature alleged to have accompanied the goods in interstate commerce was not actually shipped with the goods, as well as those where there was physical accompaniment. Of the 348 cases, 262 were seizures, 81 criminal actions, and five were suits for injunctions.

One hundred and forty-one cases, out of the total of 348, were clearly concerned with situations where the alleged accompanying labeling traveled in interstate commerce either before or after the goods or by a different means of transportation. One hundred and four of the 141 cases were seizure actions, 36 involved criminal prosecutions, and one was a suit for injunction.

The following table indicates the disposition of the 141 cases mentioned above:

SEIZURES		CRIMINAL ACTIONS	
Default Decree	74	Plea—Guilty—J/Govt	18
Consent Decree	25	Plea—Nolo—J/Govt	16
Contest—Judgment for Claimant	1	Plea—Not Guilty—J/Defendant	1
Contest—Judgment for Govt	4	Plea—Not Guilty—J/Govt	1
TOTAL	104		36

INJUNCTION

Granted 1

The two cases in which judgment was adverse to the Government were decided on grounds other than accompaniment.

> sponsibility by hiding behind the phrase "the doctors say." Couched in such language undoubtedly the printed matter makes a more persuasive appeal to the credulity of sufferers from these diseases than if the representations thus implied were made directly upon the authority alone of the proprietors, and for that reason they are not less, but more, obnoxious to the law.

This Court said in *Federal Trade Commission* v. *Standard Education Society*, 302 U. S. 112, 116:

> There is no duty resting upon a citizen to suspect the honesty of those with whom he transacts business. Laws are made to protect the trusting as well as the suspicious. The best element of business has long since decided that honesty should govern competitive enterprises, and that the rule of *caveat emptor* should not be relied upon to reward fraud and deception.

Accord: *Donaldson* v. *Read Magazine*, 333 U. S. 178, 188–189.

The only cases known to the Food and Drug Administration in which the accompaniment question was decided adverse to the Government, *Alberty* v. *United States*, 159 F. 2d 278 (C. C. A. 9), and the instant case, are as yet unreported in Notices of Judgment.

The type of literature which appeared in the accompanying labeling cases most frequently was that termed "circulars." Other kinds of written material alleged to have constituted accompanying labeling were leaflets, booklets, books, catalogs, display cards, pamphlets, placards, letters, and printed sheets.

Plainly, therefore, in a practical, every-day sense, the machines were "accompanied" by the leaflets. A person who read the leaflet would be misled to the same extent whether or not it traveled in interstate commerce in the same train, or at the same time, or over the same route, as the machine. To hold that, in such a situation as this, the Act affords no protection would merely provide a ready means for evasion of the salutary purposes of this law.

II

THE EVIDENCE AMPLY SUPPORTS THE TRIAL COURT'S FINDINGS AS TO THE FALSITY OF THE REPRESENTATIONS REGARDING DIAGNOSTIC CAPABILITIES OF THE DEVICE; THE GOVERNMENT IS THEREFORE ENTITLED TO A DECREE OF CONDEMNATION, EVEN ASSUMING THAT EVIDENCE AS TO THERAPEUTIC VALUE WAS ERRONEOUSLY EXCLUDED

The leaflets contain representations for the capabilities of the devices in two distinct fields—diagnostic and therapeutic. The Statement sets forth some of the claims of diagnostic capabilities (*supra*, pp. 6–8). With respect to the diagnostic claims, the trial court found that they represented that the devices would register the exact nature of any disease and would diagnose disease, and further found that the principles on which the machines were claimed to operate were impossible of practical application with the instruments. (R.

165–166, Findings 4–5, 7). These findings of fact do not appear to be challenged.*

The evidence which the Court of Appeals held was improperly excluded related not to the representations of diagnostic capacity but only to the representations of therapeutic value. The evidence excluded was of two types: (1) testimony of respondent's lay patients as to their condition before and after treatment with Sinuothermic machines; (2) testimony of respondent as to his diagnoses of their conditions made with the machine. As to the first type of evidence, the trial court ruled that such testimony was incompetent opinion evidence or hearsay. As to the second type of evidence, it is clear from the record that it was offered as a basis on which to show curative capabilities of the machine. (See R. 158, 160–163.) The court excluded this evidence because there was uncontradicted testimony, including testimony from the respondent, that the machine could not diagnose any specific condition. Thus, the misrepresentations as to diagnostic capacity were established in part by respondent's own admissions. His testimony was that the machines—even the ones that had meters—would not specifically diagnose what the patient's ailment

* The meaning conveyed by language used in labeling is a question of fact. *Bradley* v. *United States*, 264 Fed. 79 (C. C. A. 5); *Hall* v. *United States*, 267 Fed. 795 (C. C. A. 5); *United States* v. *John J. Fulton Co.*, 33 F. 2d 506 (C. C. A. 9); *United States* v. *7 Jugs* * * * *Rakos*, 53 F. Supp. 746, 759–760 (D. Minn.).

was (R. 129–130). He said that the device "merely locates when there is something wrong." The Government's evidence was overwhelming that the machines could not do even that. The Court of Appeals pointed out that the respondent's testimony "only claimed the machine to be an aid in diagnosing." His testimony was that the machine "only located the spot where the abnormal tissue was" after which "it was then a matter of judgment as to what the disease was" (R. 182).

The labeling claims are irreconcilable with this testimony. They assert that the machine "leaves out guess work"; that it "registers exactly and never makes a mistake"; and that it removes the necessity of having "someone guess at what your ailment is." See p. 7, *supra*. Respondent's testimony implicitly admitted that those claims are falsehoods. The Government's evidence gave them the lie explicitly. The representations as to diagnostic capacity were false and on this phase of the case alone, the Government was entitled to a decree of condemnation. Any error in the exclusion of evidence which did not disprove the making of such misrepresentations would not defeat the Government's right to condemnation.

Under the Federal Food, Drug, and Cosmetic Act it is not necessary that the Government prove that the labeling representations are both false and misleading in all respects. Petitioner is entitled to a decree of condemnation if it shows that any one of the various claims made in the labeling is

either false or misleading in any particular. Section 502 (a); *Goodwin* v. *United States*, 2 F. 2d 200, 201 (C. C. A. 6); *United States* v. *Six Dozen Bottles* * * * *Kuriko*, 158 F. 2d 667, 669–670 (C. C. A. 7); and *United States* v. *One Device* * * * *Colonic Irrigator*, 160 F. 2d 194, 200 (C. C. A. 10).

The evidence that was excluded was offered to prove that claims of therapeutic or curative value made for the machines were true (R. 158–163). The Court of Appeals concluded that the evidence from respondent as to his diagnoses was erroneously excluded because he used the machines only as an aid in diagnosing, and that the patients should have been permitted to state whether their external symptoms abated and their pains ceased (R. 182–183). The admission of the evidence within those limits would have had no bearing upon the capabilities of the machines as instruments for diagnosing disease.

Since it appears from the undisputed testimony and from the admissions of the respondent that the machines are incapable of diagnosing specific conditions, and since the machines were represented as having such diagnostic capabilities, petitioner is entitled to a decree of condemnation if it prevails on the "accompaniment" issue, irrespective of whether the court below was correct in holding other evidence relating to the curative value of the machines improperly ex-

cluded. The respondent was not prejudiced by the exclusion of this evidence and the ruling of the trial court is not reversible. *Ross Lumber Co.* v. *Hughes Lumber Co.,* 264 Fed. 757, 760 (C. C. A. 5), certiorari denied, 254 U. S. 635; *Nalbantian* v. *United States,* 54 F. 2d 63, 64 (C. C. A. 7), certiorari denied, 285 U. S. 536; *Jennings* v. *United States,* 73 F. 2d 470, 471 (C. C. A. 5). Accord: *Holloway* v. *Dunham,* 170 U. S. 615, 618.

Furthermore, the decision below on the "accompaniment" issue calls for a dismissal of this libel. If the court below was wrong on that point but correct in reversing the judgment because of the exclusion of evidence, respondent would at most be entitled to a new trial at which the excluded evidence could be admitted. We believe, however, that the court below is in error on both points, and that the judgment of the district court is correct.

CONCLUSION

For the reasons stated it is respectfully submitted that the judgment of the Court of Appeals should be reversed, and that of the district court reinstated.

PHILIP B. PERLMAN,
Solicitor General.
ALEXANDER M. CAMPBELL,
Assistant Attorney General.
PHILIP ELMAN,
Special Assistant to the Attorney General.
WILLIAM W. GOODRICH,
BERNARD D. LEVINSON,
Attorneys, Federal Security Agency.

SEPTEMBER 1948.

APPENDIX

STATUTE AND REGULATION INVOLVED

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040 (21 U. S. C. 301, et seq.), and regulations issued thereunder follow:

SEC. 201. For the purposes of this Act—

* * * * *

(h) The term "device" * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

* * * * *

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article;

* * *

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

* * * * *

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but, if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *

SEC. 502. A drug or device shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular.

* * * * *

(f) Unless its labeling bears (1) adequate directions for use; * * *

REGULATION

21 C. F. R. Cum. Supp. §2.2 Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

U. S. GOVERNMENT PRINTING OFFICE: 1948